

REMARKS

Applicant has carefully reviewed the Examiner's August 29, 2003, Official Action and respectfully requests reconsideration based on the above amendments and the following comments.

Claims 9-16 remain in the application for consideration.

The Examiner has rejected claims 9-16 under 35 U.S.C. 102(B) as being anticipated by Scheibel (US 3,396,475). Applicant respectfully traverses this rejection based on the following comments.

A. The freeze-drying apparatus of the present invention is based on the concept of drying the liquid material (such as medicaments, etc.) under the vacuum-controlled condition, which is sprayed and frozen onto the inner surface of the chamber constituted with a plurality of cylindrical tubes, each being equipped with the jacket.

1) The specific feature of the freeze-drying apparatus of the present invention resides in that the liquid material to be freeze-dried is sprayed through the nozzle by the thin film falling system in such a manner that the liquid material is sprayed and frozen to adhere onto the ice-lining, (layer) which has been frozen beforehand onto the inner surface of the cylindrical tubes from the top of this tube

down to its bottom, with a uniform film thickness. (The technique of forming the ice-lining has already been patented in 1989 under U.S. Patent No. 4,802,286 by the same applicant).

2) The drying step, is the same as the conventional freeze-drying process, is done by the sublimation system, in which the multiple-series of tubes are each heated from its lateral side with a heat medium to thereby sublimate water content (moisture) from the frozen surface of the liquid material within the inner cavity of the tubes (the water vapor being recovered by the cold trap).

B. In contrast to this, the cited patent to Scheibel teaches a series of steps of spraying the preliminarily cooled material into the chamber (tubes) from its top part, while a high temperature inert gas is introduced from its bottom part to sublimate the liquid material by heat-exchange between the two substances, and the water vapor is recovered by means of a heat-exchanger in the form of water.

As is understandable from the above, the freeze-drying of the liquid material according to the present invention differs from the cited reference patent in its fundamental principle, so that the present invention is in no way anticipated by the cited patent to Scheibel.

While both inventions appear similar in their external appearance, they are quite different in their inventive concept. More specifically, while the present invention relies on the freeze-drying technique under the vacuum condition (or lyophilization), the Scheibel's system does not teach the drying under the vacuum condition, but the spray-drying system under the slightly negative pressure (sub-atmospheric) condition. Hence, it is no exaggeration to say that the Scheibel's system is of no use at all for the production of medicaments, etc., where stringent requirement is imposed to secure germ-free as well as dust-free state.

To sum up the differences between the present invention and the cited patent to Scheibel, the following comparative table will be shown.

| <u>Point of Difference</u>                                 | <u>Present<br/>Invention</u>               | <u>USP 3,396,475<br/>(Scheibel)</u>  |
|--|--|--|
| 1. Ice-Lining  | Material is freeze-dried on the ice-lining | None [cooled liquid material is introduced from top of chamber, while inert gas (0°C ) from its bottom, material being sublimated by heat-exchange to produce water-vapor which is recovered in the form of water] |
| 2. Pressure within (frozen):<br>drying (dried):<br>chamber | Atmospheric<br>Vacuum                      | Sub-atmospheric<br>Sub-atmospheric   |

|                                       |  |  |
|---------------------------------------|--|--|
| 3 Concept of freezing                 | Pre-freezing   | Self-freezing  |
| 4 Concept of drying                   | Water vapor is taken out by difference of vapor saturation pressure under vacuum                     | Water vapor is removed by gas cycle  |
| 5 Freezing temp.                      | Depending on material used, at same temp. (e.g. -40°C)   | Depending on material used, at varying temp. (e.g. -2.5°C ~-6.7°C; -28.9 °C; -40 °C) |
| 6 Drying temp.                        | Depending upon material used (e.g. 0 °C in 1 <sup>st</sup> stage; and 20°C in 2 <sup>nd</sup> stage) | Depending on material used, at varying temp. (e.g. -2.5°C ~-6.7°C; -28.9 °C; -40 °C) |
| 7 State of (frozen): product(dried) : | Cylindrical<br>Cylindrical (bfr crushing)  | Powder<br>Powder   |

From the above comparison, it will be seen that the present invention is remarkably different from the cited patent to Scheibel, the latter teaching the idea of neither forming the "ice-lining", nor attaching the liquid material onto this ice-lining in uniform thickness, hence the present invention is sufficiently patentable over the cited prior art.

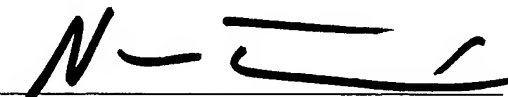
Appln. No. 10/035,421  
Amdt. dated December 1, 2003  
Reply to Office Action of August 29, 2003

Applicant submits that the invention is new and unobvious and not disclosed by the cited art. Accordingly, Applicant respectfully solicits the Examiner's early review and issuance of this application.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant(s)

By



Norman J. Latker  
Registration No. 19,963

NJL:ft

G:\BN\N\Niiz\akimoto4\pto\Amendment 01Dec03.doc

Telephone No.: (202) 628-5197

Facsimile No.: (202) 737-3528